

AMENDED IN SENATE AUGUST 21, 2012
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CALIFORNIA LEGISLATURE—2011–12 REGULAR SESSION

ASSEMBLY BILL

No. 1442

**Introduced by Assembly Member Wieckowski
(Coauthors: Assembly Members Allen and Williams)**

January 4, 2012

An act to amend Sections 117935, 117945, 117960, 118000, 118040, and 118165 of, and to add Sections 117637, 117748, 118032, and 118033 to, the Health and Safety Code, relating to pharmaceutical waste.

LEGISLATIVE COUNSEL'S DIGEST

AB 1442, as amended, Wieckowski. Pharmaceutical waste.

The existing Medical Waste Management Act, administered by the State Department of Public Health, regulates the management and handling of medical waste, as defined. Existing law requires that all medical waste be hauled by either a registered hazardous waste hauler or by a person with an approved limited-quantity exemption granted pursuant to specified provisions of law. Violation of these provisions of law is a crime.

This bill would define pharmaceutical waste for purposes of the Medical Waste Management Act, and would exempt a pharmaceutical waste generator or parent organization that employs health care

professionals who generate pharmaceutical waste from specified medical waste hauling requirements if the generator, health care professional, or parent organization retains specified documentation and meets specified requirements and if the facility receiving the medical waste retains specified documentation and meets specified requirements. The bill would authorize pharmaceutical waste to be transported by the generator or health care professional who generated the pharmaceutical waste, a staff member of the generator or health care professional, or common carrier, as defined, pursuant to these provisions. By expanding the definition of a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 117637 is added to the Health and Safety
- 2 Code, to read:
- 3 117637. "Common carrier" means either of the following:
- 4 (a) A person or company that has a United States Department
- 5 of Transportation number issued by the Federal Motor Carrier
- 6 Safety Administration and is registered with the Federal Motor
- 7 Carrier Safety Administration as a for-hire property carrier.
- 8 (b) A person or company that has a motor carrier of property
- 9 permit issued by the Department of Motor Vehicles pursuant to
- 10 the Motor Carriers of Property Permit Act (Division 14.85
- 11 (commencing with Section 34600) of the Vehicle Code) and, if
- 12 applicable, a carrier identification number issued by the Department
- 13 of the California Highway Patrol pursuant to Section 34507.5 of
- 14 the Vehicle Code.
- 15 SEC. 2. Section 117748 is added to the Health and Safety Code,
- 16 to read:
- 17 117748. (a) "Pharmaceutical waste" means any pharmaceutical,
- 18 as defined in Section 117747, ~~that for any reason may no longer~~

1 ~~be sold or dispensed for use as a drug is a waste, as defined in~~
2 ~~Section 25124.~~

3 (b) For purposes of this part, “pharmaceutical waste” does not
4 include any pharmaceutical that ~~is outdated or nonsalable and is~~
5 ~~being returned to a reverse distributor, as defined in Section 4040.5~~
6 ~~of the Business and Professions Code, that is licensed both as a~~
7 ~~wholesaler of dangerous drugs by the California State Board of~~
8 ~~Pharmacy pursuant to Section 4160 of the Business and Professions~~
9 ~~Code and as a permitted transfer station pursuant to Section~~
10 ~~117775, for possible manufacturer credit. meets either of the~~
11 ~~following criteria:~~

12 (1) ~~The pharmaceutical is being sent out of the State of~~
13 ~~California to a reverse distributor, as defined in Section 4040.5~~
14 ~~of the Business and Professions Code, that is licensed as a~~
15 ~~wholesaler of dangerous drugs by the California State Board of~~
16 ~~Pharmacy pursuant to Section 4161 of the Business and~~
17 ~~Professions Code.~~

18 (2) ~~The pharmaceutical is being sent by a reverse distributor,~~
19 ~~as defined in Section 4040.5 of the Business and Professions Code,~~
20 ~~offsite for treatment and disposal in accordance with applicable~~
21 ~~laws, or to a reverse distributor that is licensed as a wholesaler~~
22 ~~of dangerous drugs by the California State Board of Pharmacy~~
23 ~~pursuant to Section 4160 of the Business and Professions Code~~
24 ~~and as a permitted transfer station if the reverse distributor is~~
25 ~~located within the State of California.~~

26 SEC. 3. Section 117935 of the Health and Safety Code is
27 amended to read:

28 117935. Any small quantity generator required to register with
29 the enforcement agency pursuant to Section 117930 shall file with
30 the enforcement agency a medical waste management plan, on
31 forms prescribed by the enforcement agency containing, but not
32 limited to, all of the following:

- 33 (a) The name of the person.
34 (b) The business address of the person.
35 (c) The type of business.
36 (d) The types, and the estimated average monthly quantity, of
37 medical waste generated.
38 (e) The type of treatment used onsite.
39 (f) The name and business address of the registered hazardous
40 waste hauler used by the generator for backup treatment and

1 disposal, for waste when the onsite treatment method is not
2 appropriate due to the hazardous or radioactive characteristics of
3 the waste, the name of the registered hazardous waste hauler used
4 by the generator to have untreated medical waste removed for
5 treatment and disposal, and, if applicable, the name of the common
6 carrier used by the generator to transport pharmaceutical waste
7 offsite for treatment and disposal pursuant to Section 118032.

8 (g) A statement indicating that the generator is hauling the
9 medical waste generated in his or her business pursuant to Section
10 118030 and the name and any business address of the treatment
11 and disposal facilities to which the waste is being hauled, if
12 applicable.

13 (h) The name and business address of the registered hazardous
14 waste hauler service provided by the building management to
15 which the building tenants may subscribe or are required by the
16 building management to subscribe and the name and business
17 address of the treatment and disposal facilities used, if applicable.

18 (i) A statement certifying that the information provided is
19 complete and accurate.

20 SEC. 4. Section 117945 of the Health and Safety Code is
21 amended to read:

22 117945. Small quantity generators who are not required to
23 register pursuant to this chapter shall maintain on file in their office
24 all of following:

25 (a) An information document stating how the generator contains,
26 stores, treats, and disposes of any medical waste generated through
27 any act or process of the generator.

28 (b) Records of any medical waste transported offsite for
29 treatment and disposal, including the quantity of waste transported,
30 the date transported, the name of the registered hazardous waste
31 hauler or individual hauling the waste pursuant to Section 118030,
32 and, if applicable, the name of the common carrier transporting
33 pharmaceutical waste pursuant to Section 118032. The small
34 quantity generator shall maintain these records for not less than
35 two years.

36 SEC. 5. Section 117960 of the Health and Safety Code is
37 amended to read:

38 117960. Any large quantity generator required to register with
39 the enforcement agency pursuant to Section 117950 shall file with
40 the enforcement agency a medical waste management plan, on

forms prescribed by the enforcement agency containing, but not limited to, all of the following:

- (a) The name of the person.
- (b) The business address of the person.
- (c) The type of business.
- (d) The types, and the estimated average monthly quantity, of medical waste generated.
- (e) The type of treatment used onsite, if applicable. For generators with onsite medical waste treatment facilities, including incinerators or steam sterilizers or other treatment facilities as determined by the enforcement agency, the treatment capacity of the onsite treatment facility.
- (f) The name and business address of the registered hazardous waste hauler used by the generator to have untreated medical waste removed for treatment, if applicable, and, if applicable, the name and business address of the common carrier transporting pharmaceutical waste pursuant to Section 118032.
- (g) The name and business address of the registered hazardous waste hauler service provided by the building management to which the building tenants may subscribe or are required by the building management to subscribe, if applicable.
- (h) The name and business address of the offsite medical waste treatment facility to which the medical waste is being hauled, if applicable.
- (i) An emergency action plan complying with regulations adopted by the department.
- (j) A statement certifying that the information provided is complete and accurate.

SEC. 6. Section 118000 of the Health and Safety Code is amended to read:

118000. (a) Except as otherwise exempted pursuant to Section 118030 or 118032, all medical waste transported to an offsite medical waste treatment facility shall be transported in accordance with this chapter by a registered hazardous waste transporter issued a registration certificate pursuant to Chapter 6 (commencing with Section 118025) and Article 6.5 (commencing with Section 25167.1) of Chapter 6.5 of Division 20. A hazardous waste transporter transporting medical waste shall have a copy of the transporter's valid hazardous waste transporter registration certificate in the transporter's possession while transporting

1 medical waste. The transporter shall show the certificate, upon
2 demand, to any enforcement agency personnel or authorized
3 employee of the Department of the California Highway Patrol.

4 (b) Except for small quantity generators transporting medical
5 waste pursuant to Section 118030 or small quantity generators or
6 common carriers transporting pharmaceutical waste pursuant to
7 Section 118032, medical waste shall be transported to a permitted
8 offsite medical waste treatment facility or a permitted transfer
9 station in leak-resistant and fully enclosed rigid secondary
10 containers that are then loaded into an enclosed cargo body.

11 (c) A person shall not transport medical waste in the same
12 vehicle with other waste unless the medical waste is separately
13 contained in rigid containers or kept separate by barriers from
14 other waste, or unless all of the waste is to be handled as medical
15 waste in accordance with this part.

16 (d) Medical waste shall only be transported to a permitted
17 medical waste treatment facility, or to a transfer station or another
18 registered generator for the purpose of consolidation before
19 treatment and disposal, pursuant to this part.

20 (e) Facilities for the transfer of medical waste shall be annually
21 inspected and issued permits in accordance with the regulations
22 adopted pursuant to this part.

23 (f) Any persons manually loading or unloading containers of
24 medical waste shall be provided by their employer at the beginning
25 of each shift with, and shall be required to wear, clean and
26 protective gloves and coveralls, changeable lab coats, or other
27 protective clothing. The department may require, by regulation,
28 other protective devices appropriate to the type of medical waste
29 being handled.

30 SEC. 7. Section 118032 is added to the Health and Safety Code,
31 to read:

32 118032. A pharmaceutical waste generator or parent
33 organization that employs health care professionals who generate
34 pharmaceutical waste is exempt from the requirements of
35 subdivision (a) of Section 118000 if all of the following
36 requirements are met:

37 (a) The generator or parent organization has on file one of the
38 following:

39 (1) If the generator or parent organization is a small quantity
40 generator required to register pursuant to Chapter 4 (commencing

1 with Section 117915), a medical waste management plan prepared
2 pursuant to Section 117935.

3 (2) If the generator or parent organization is a small quantity
4 generator not required to register pursuant to Chapter 4
5 (commencing with Section 117915), the information document
6 maintained pursuant to subdivision (a) of Section 117945.

7 (3) If the generator or parent organization is a large quantity
8 generator, a medical waste management plan prepared pursuant
9 to Section 117960.

10 (b) The generator or health care professional who generated the
11 pharmaceutical waste transports the pharmaceutical waste himself
12 or herself, or directs a member of his or her staff to transport the
13 pharmaceutical waste to a parent organization or another health
14 care facility for the purpose of consolidation before treatment and
15 disposal, or contracts with a common carrier to transport the
16 pharmaceutical waste to a permitted medical waste treatment
17 facility or transfer station.

18 (c) Except as provided in subdivision (d), all of the following
19 requirements are met:

20 (1) Prior to shipment of the pharmaceutical waste, the generator
21 notifies the intended destination facility that it is shipping
22 pharmaceutical waste to it and provides a copy of the tracking
23 document, as specified in Section 118040.

24 (2) The generator and the facility receiving the pharmaceutical
25 waste maintain the tracking document, as specified in Section
26 118040.

27 (3) The facility receiving the pharmaceutical waste notifies the
28 generator of the receipt of the pharmaceutical waste shipment and
29 any discrepancies between the items received and the tracking
30 document, as specified in Section 118040, evidencing diversion
31 of the pharmaceutical waste.

32 (4) The generator notifies the enforcement agency of any
33 discrepancies between the items received and the tracking
34 document, as specified in Section 118040, evidencing diversion
35 of the pharmaceutical waste.

36 (d) (1) Notwithstanding subdivision (c), if a health care
37 professional who generates pharmaceutical waste returns the
38 pharmaceutical waste to the parent organization for the purpose
39 of consolidation before treatment and disposal over a period of
40 time, a single-page form or multiple entry log may be substituted

1 for the tracking document, if the form or log contains all of the
2 following information:

3 (A) The name of the person transporting the pharmaceutical
4 waste.

5 (B) The number of containers of pharmaceutical waste. This
6 clause does not require any generator to maintain a separate
7 pharmaceutical waste container for every patient or to maintain
8 records as to the specified source of the pharmaceutical waste in
9 any container.

10 (C) The date that the pharmaceutical waste was returned.

11 (2) The form or log described in paragraph (1) shall be
12 maintained in the files of the health care professional who generates
13 the pharmaceutical waste and the parent organization or another
14 health care facility that receives the pharmaceutical waste.

15 (3) This subdivision does not prohibit the use of a single
16 document to verify the return of more than one container to a parent
17 organization or another health care facility, provided the form or
18 log meets the requirements specified in paragraphs (1) and (2).

19 SEC. 8. Section 118033 is added to the Health and Safety Code,
20 to read:

21 118033. The pharmaceutical waste that is separated from
22 medical waste by the generator shall be maintained in a manner
23 to secure the pharmaceutical waste contents from access by
24 unauthorized individuals. Any suspected or confirmed tampering
25 of, unauthorized access to, or loss of this pharmaceutical waste
26 shall be reported to the appropriate state licensing authority.

27 SEC. 9. Section 118040 of the Health and Safety Code is
28 amended to read:

29 118040. (a) Except with regard to sharps waste consolidated
30 by a home-generated sharps consolidation point approved pursuant
31 to Section 117904, a hazardous waste transporter or generator
32 transporting medical waste shall maintain a completed tracking
33 document of all medical waste removed for treatment or disposal.
34 A hazardous waste transporter or generator who transports medical
35 waste to a facility, other than the final medical waste treatment
36 facility, shall also maintain tracking documents which show the
37 name, address, and telephone number of the medical waste
38 generator, for purposes of tracking the generator of medical waste
39 when the waste is transported to the final medical waste treatment
40 facility. At the time that the medical waste is received by a

1 hazardous waste transporter, the transporter shall provide the
2 medical waste generator with a copy of the tracking document for
3 the generator's medical waste records. The transporter or generator
4 transporting medical waste shall maintain its copy of the tracking
5 document for three years.

6 (b) The tracking document shall include, but not be limited to,
7 all of the following information:

8 (1) The name, address, telephone number, and registration
9 number of the transporter, unless transported pursuant to Section
10 118030.

11 (2) The type of medical waste transported and the quantity or
12 aggregate weight of medical waste transported.

13 (3) The name, address, and telephone number of the generator.

14 (4) The name, address, telephone number, permit number, and
15 the signature of an authorized representative of the permitted
16 facility receiving the medical waste.

17 (5) The date that the medical waste is collected or removed
18 from the generator's facility, the date that the medical waste is
19 received by the transfer station, the registered large quantity
20 generator, or point of consolidation, if applicable, and the date that
21 the medical waste is received by the treatment facility.

22 (c) Any hazardous waste transporter or generator transporting
23 medical waste in a vehicle shall have a tracking document in his
24 or her possession while transporting the medical waste. The
25 tracking document shall be shown upon demand to any
26 enforcement agency personnel or officer of the Department of the
27 California Highway Patrol. If the medical waste is transported by
28 rail, vessel, or air, the railroad corporation, vessel operator, or
29 airline shall enter on the shipping papers any information
30 concerning the medical waste that the enforcement agency may
31 require.

32 (d) A hazardous waste transporter or a generator transporting
33 medical waste shall provide the facility receiving the medical waste
34 with the original tracking document.

35 (e) Each hazardous waste transporter and each medical waste
36 treatment facility shall provide tracking data periodically and in a
37 format as determined by the department.

38 (f) Medical waste transported out of state shall be consigned
39 to a permitted medical waste treatment facility in the receiving
40 state. If there is no permitted medical waste treatment facility in

1 the receiving state or if the medical waste is crossing an
2 international border, the medical waste shall be treated in
3 accordance with Chapter 8 (commencing with Section 118215)
4 prior to being transported out of the state.

5 SEC. 10. Section 118165 of the Health and Safety Code is
6 amended to read:

7 118165. On and after April 1, 1991, all persons operating a
8 medical waste treatment facility shall maintain individual records
9 for a period of three years and shall report or submit to the
10 enforcement agency upon request, all of the following information:

11 (a) The type of treatment facility and its capacity.

12 (b) All treatment facility operating records.

13 (c) Copies of the tracking documents for all medical waste it
14 receives for treatment from offsite generators, hazardous waste
15 haulers, or, pursuant to Section 118032, common carriers.

16 SEC. 11. No reimbursement is required by this act pursuant to
17 Section 6 of Article XIII B of the California Constitution because
18 the only costs that may be incurred by a local agency or school
19 district will be incurred because this act creates a new crime or
20 infraction, eliminates a crime or infraction, or changes the penalty
21 for a crime or infraction, within the meaning of Section 17556 of
22 the Government Code, or changes the definition of a crime within
23 the meaning of Section 6 of Article XIII B of the California
24 Constitution.